OCT - 3 2003

K032776
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510(k) Summary
for
Vacurect Vacuum Constriction Device

1. SPONSOR

Vacurect Manufacturing (PTY) Ltd.
730 Tetra Avenue
Moreletapark, Pretoria
Republic of South Africa
Postal Address: P.O. Box 39385
Moreletapark 0044
Republic of South Africa

2. DEVICE NAME

Proprietary Name:	Vacurect Vacuum Constriction Device
Common/Usual Name:	External Penile Rigidity Device
Classification Name:	Vacuum Pump and Constriction Rings
Submission Date:	September 4, 2003

3. PREDICATE DEVICES

Repro-Med Restore Vacuum Erection Device (K981506)

Imagyn Medical Technologies, Inc. Impower System Vacuum Erection System (K980291)

4. DEVICE DESCRIPTION

The Vacurect Vacuum Constriction Device is an over the counter device that consists of two main components: the vacuum tube and the constriction ring. The vacuum tube consists of the pump sleeve, spacer ring, dome/sleeve O-Rings, dome/valve stopper, and vacuum ring.

The Vacurect Vacuum Constriction Device works by creating a vacuum in the vacuum tube. This is accomplished by moving the pump sleeve up and down along the vacuum tube. The flexible rubber constriction ring when placed onto the vacuum tube (open end), forms an airtight seal with the vacuum tube. Once the opening of

the constriction ring is placed on the penis head, the vacuum chamber is sealed and operation of the pump sleeve will immediately draw the penis into the vacuum tube.

Once the required penis rigidity is reached, the vacuum pump may be removed and the ring can remain on the penis for up to 30 minutes.

5. INTENDED USE

The Vacurect vacuum component is intended to create an erection in men with erectile dysfunction by means of an applied vacuum to the penis. The constriction ring is intended to maintain penile rigidity in men with erectile dysfunction.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Vacurect Vacuum Constriction Device and the predicate devices all use a vacuum tube and constriction ring to create and maintain an erection in men with erectile dysfunction. The Vacurect vacuum tube is similar to the predicate devices in that it is made of a smooth plastic material that provides an airtight seal with the penis during use. The constriction ring is also similar to the predicate devices in that they are all designed to restrict penis venous outflow after the patient has obtained an erection with the aid of a vacuum pump.

7. PERFORMANCE TESTING

Testing was performed to determine that the pumping mechanism does not create a vacuum greater than 0.57 bar = 17 inches.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2003

Vacurect Manufacturing (PTY) Ltd.
c/o Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K032776
Trade/Device Name: Vacurect Vacuum Constriction Device
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LKY
Dated: September 4, 2003
Received: September 12, 2003

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032776

Device Name: Vacurect Vacuum Constriction Device

Indications for Use:

The Vacurect vacuum component is intended to create an erection in men with erectile dysfunction by means of an applied vacuum to the penis. The constriction ring is intended to maintain penile rigidity in men with erectile dysfunction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032776

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)